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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,254	02/18/2004	Joel E. Bernstein	41959-102742	3157

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
05/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/781,254	BERNSTEIN, JOEL E.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 14, 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *8-10,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/18/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed February 14, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 1-7, 11 and 12 under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn.

The rejection of claims 1-7, 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission in view of Midha et al. (1992) of record is being maintained for the reasons stated in the previous Office Action.

Applicant's amendment necessitated additional rejection presented in this Office action.

Response to Arguments

Applicant's arguments filed February 14, 2008 have been fully considered but they are not persuasive. Applicant argues that the meaning of the word "preponderance" in the application includes "majority", so a proposal to amend claims to "at least 51% cis" was made to overcome the rejection under 35 U.S.C. 112, 2nd paragraph. This is not found persuasive because the phrase "at least 51% cis" lack literal support in the specification

as instantly filed. Therefore, the New Matter rejection made in this Office Action is deemed proper. Applicant argues that the Midha reference merely states that the cis-isomer is more active than the trans isomer and yet the prior art doxepin composition having predominantly trans isomer can be used to treat insomnia. Therefore, these two references, taken together, actually teach away from the instant invention because they suggest that cis-doxepin would have a greater sedative effect, not a lesser effect as recited in the claims. This is not found persuasive because the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, instant claims are drawn to “composition" claims comprising “preponderance of cis-isomer of doxepin” **not** "method” claims comprising “preponderance of cis-isomer of doxepin”. Therefore, it would have been obvious to one of ordinary skill in the art to formulate doxepin comprising substantially more of the cis form of doxepin than trans-doxepin for the treatment of disorder (e.g. affective disorders) because cis-doxepin is more active than trans as disclosed by Midha et al. The motivation to employ cis-doxepin because of its potency need not be Applicants' motivation to invent of exhibiting less sedation for the determination of patentability for the "composition" claims. One of ordinary skill in the art would have been motivated to employ the composition comprising substantially more of cis isomer than trans isomer of doxepin including "pure" cis isomer in order to achieve a more potent effect in the treatment of affective disorder compared to predominately trans-isomer of doxepin.

Since there is no upper limit of cis-isomer present, instant claims encompasses the employment of "pure" or "99.9%" of cis-isomer. The Declaration under 37 CFR 1.132 has been carefully reviewed and considered. However, it is not persuasive because the "evidence" of surprising and unexpected result is not commensurate in scope with the breadth of the claims. It is well established that a showing of unexpected results generally must be commensurate in scope with the breadth of the claims sought to be patented. See, inter alia, (1) In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (showing of unexpected results must be commensurate in scope with breadth of claim); (2) In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990) (same); and (3) In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (same). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "at least 51%" lack literal support in the specification as originally filed.

This is a New Matter rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission in view of Midha et al. (1992) of record .

Applicant admits that doxepin hydrochloride is most frequently used to treat the affective disorders depression and also employed less commonly for a treatment of a variety of painful and allergic disorder. (specification page 1, lines 4-7). Applicant admits that doxepin is generally used topical application or ingestion formulation. (specification page 1, lines 8-10). Applicants admit that doxepin hydrochloride U.S.P. is a geometric isomer mixture "containing not less than 13.7% and not more than 18.1% of the cis isomer and "not less than 81.4% and not more than 88.2% of the trans isomer. (specification page 1, lines 14-18). Applicants also admit that the systemic side effects (i.e. sedation) of doxepin occur in from 20% to over 60%, depending upon dosage and route of doxepin administration.

The difference between the primary reference and Applicant's claiming invention is amounts of cis doxepin isomer being "preponderance" over trans doxepin isomer and the degree of sedation effect of claims 1 and 11, the pharmaceutical formulations such as lotion, solution or cream etc., the amount of cis-isomer.

Midha et al. disclose that cis-doxepin component of the tricyclic anti-depressant doxepin is more active than trans-isomer. (abstract).

It would have been obvious to one of ordinary skill in the art to formulate doxepin comprising substantially more of the cis form of doxepin than trans-doxepin for the treatment of disorders (e.g. affective disorders) indicated to be effective with doxepin because cis-doxepin is more active than trans as disclosed by Midha et al. One would have been motivated to employ the composition comprising substantially more of cis isomer than trans isomer of doxepin to achieve at least comparable or superior benefit in the treatment of affective disorder therapy. The degree of desired sedation is obvious because as admitted by the Applicant that sedation of doxepin depends upon dosage and the route of doxepin administration as well known in the art by Applicant's admission. Moreover, the amounts of active agents to be used and the pharmaceutical forms, e.g., tablets, lotion etc; mode of administration are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations of commercially available doxepin formulation and modes of administration.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
May 9, 2008